Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A method for determining if a human has ~~the presence of~~ an acute ischemic renal tubular cell injury that can progress to acute renal failure (ARF) ~~in a mammal, including an ischemic renal injury and a nephrotoxic injury~~, comprising the steps of:

(a) providing a urine sample obtained from a human within a period of time of about 12 hours after an event that can cause ~~mammalian subject that is suspected of having~~ an acute ischemic renal tubular cell injury, and that predisposes the human to progressing to ARF, the event selected from the group consisting of (a) a surgical procedure selected from the group consisting of open heart surgery, cardiac surgery, and vascular surgery, and (b) kidney transplantation;

(b) contacting the urine sample with an antibody for neutrophil gelatinase-associated lipocalin (NGAL), to allow formation of a complex of the antibody and the NGAL;

(c) detecting the antibody-NGAL complex; and

(d) correlating [[the]] an elevated level of detected antibody-NGAL complex to the human having ~~presence of~~ the acute ischemic renal tubular cell injury that can progress to ARF.

2. (previously presented) The method according to Claim 30 wherein the urine sample comprises a plurality of urine samples from the subject that are obtained intermittently or continuously.

3. (canceled)

4. (previously presented) The method according to Claim 31 wherein the step of detecting the antibody-NGAL complex comprises contacting the complex with a second antibody for detecting the NGAL.

5. (previously presented) The method according to Claim 30 wherein the mammalian subject is a human.

6. - 8. (canceled)

9. (currently amended) The method according to Claim 31 wherein the antibody is a capture antibody for the NGAL and the antibody-NGAL complex is a capture antibody-NGAL complex.

10. (previously presented) The method according to Claim 9 wherein the step of detecting the antibody-NGAL complex comprises the steps of:

(1) separating any unbound material of the urine sample from the capture antibody-NGAL complex;

(2) contacting the capture antibody-NGAL complex with a second antibody for detecting the NGAL, to allow formation of a second complex between the second antibody and the capture antibody-NGAL complex;

(3) separating any unbound second antibody from the second antibody complex; and

(4) detecting the second antibody of the second antibody complex.

11. (previously presented) The method according to Claim 10 wherein the step (i) comprises the step of contacting the urine sample with a media having affixed thereto the capture antibody.

12. – 29. (cancelled)

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30. (currently amended) A method for determining if a mammalian subject has ~~the presence of~~ an acute ischemic renal tubular cell injury that can progress to acute renal failure (ARF) ~~in a mammalian subject~~, wherein the method comprises the steps of:

(a) detecting the quantity ~~presence~~ of any neutrophil gelatinase-associated lipocalin (NGAL) in a urine sample obtained from a mammalian subject within a period of time of about 12 hours after an event that is suspected of causing ~~having~~ an acute ischemic renal tubular cell injury, and that predisposes the mammalian subject to progressing to ARF; and

(b) correlating an elevated quantity ~~the presence of~~ NGAL in the urine sample to the mammalian subject having ~~presence of~~ the acute ischemic renal tubular cell injury that can progress to ARF.

31. (currently amended) The method according to claim 30, wherein the detecting of the quantity of NGAL is done by

(i) contacting the urine sample with an antibody for NGAL to allow formation of a complex of the antibody with any NGAL present in the urine sample; and

(ii) detecting the antibody-NGAL complex as a measure of a [[the]] level of the NGAL.

32. (canceled)

33. (currently amended) The method according to claim 30, wherein the ~~method is used to detect NGAL present in a~~ obtained urine sample is [[of]] the first urine output of the subject immediately following the event ~~acute renal tubular cell injury~~.

34. (canceled)

35. (currently amended) The method according to claim 30 wherein ~~the urine sample is obtained within a period of time following the acute renal tubular cell injury,~~ the period of time is selected from the group consisting of 6 hours, 4 hours, 3 hours, 2 hours, 1 hour, and 30 minutes.

36. (canceled)

37. (currently amended) The method according to claim 30 [[36]] wherein the event is selected from the group consisting of: (a) a surgical procedure selected from the group consisting of open heart surgery, cardiac surgery, ~~coronary bypass surgery,~~ and vascular surgery; and (b) kidney transplantation~~; (c) administration of a nephrotoxic agent; (d) a cardiovascular event; and (e) a condition selected from the group consisting of stroke, trauma, sepsis, and dehydration~~.

38. – 47. (canceled)

48. (currently amended) The method according to claim 1 wherein the step of detecting the antibody-NGAL complex ~~further~~ comprises determining the level of the antibody-NGAL complex, and wherein the step of correlating comprises correlating the elevated level of the antibody-NGAL complex to ~~the extent of~~ the acute ischemic renal tubular cell injury that can progress to ARF.

49. – 51. (canceled)

52. (previously presented) The method according to claim 30, wherein the urine sample is an unprocessed urine sample.

53. – 54. (canceled)

55. (currently amended) The method according to claim 31 wherein the level of NGAL correlates with the extent of the acute ischemic renal tubular cell injury.

56. – 59. (canceled)

60. (new) The method according to claim 1 wherein the elevated level of antibody-NGAL complex is at least a 10-fold increase in the level of antibody-NGAL complex.

61. (new) The method according to claim 30 wherein the elevated quantity of NGAL is at least a 10-fold increase in the level of NGAL.

62. (new) The method according to claim 1, wherein the urine sample is an unprocessed urine sample.

63. (new) The method according to claim 35 wherein the period of time is selected from the group consisting of 3 hours, 2 hours, 1 hour, and 30 minutes.

64. (new) The method according to claim 1 wherein the period of time is selected from the group consisting of 3 hours, 2 hours, 1 hour, and 30 minutes.

65. (new) The method according to claim 30 wherein the elevated quantity of NGAL is significantly elevated above a smaller increased quantity of NGAL in a mammalian subject having an acute ischemic renal tubular cell injury that does not progress to ARF.